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Jaan Noolandi

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EXAMINER

SKORUPA, VALERIE LYNN

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/740,209	<b>Applicant(s)</b> NOOLANDI ET AL.	
	<b>Examiner</b> VALERIE L. SKORUPA	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-17,19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-17,19 and 21-26 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1, 2, 4, 9-11, 13, 19, 21, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Gauthier et al. (US Patent No. 3,387,607).**

As to claim 1, Gauthier discloses an apparatus (Fig. 1-7) for delivering a pharmaceutical product comprising: a first driver element 12, 120 (Fig. 6) to generate acoustic energy (col. 3, ln. 73 - col. 4, ln. 4) in pulses that are of a short duration and low frequency such that a droplet of pharmaceutical product is output from a capillary wave (Gauthier discloses that the frequency of the transducer is adjustable via the oscillator 14 (col. 6, ln. 32-44) and therefore, it appears that the device is capable of performing this function); a first acoustic lens 121 (Fig. 6, col. 7, ln. 7-10) positioned between the first driver element 120 and the capillary wave (see Fig. 6 which shows the lens 121 between the transducer 120 and the surface of the liquid (near 40), where the wave would form); and a delivery system (the housing of the device) to maintain the pharmaceutical product in a position to receive the acoustic energy from the first acoustic lens and cause ejection of the droplet of pharmaceutical product.

As to claim 2, Gauthier discloses a source of electric power 123, 124 coupled to the first driver element 121 (Fig. 6, col. 7, ln. 10-15).

As to claim 4, Gauthier discloses that the first acoustic lens is a plastic lens (col. 7, ln. 7-10).

As to claim 9, Gauthier discloses the claimed invention, as discussed in claim 1 above, including that the driver element 12, 120 is programmed to output acoustic energy at a frequency below 15 MHz (col. 4, ln. 26-31).

As to claim 10, Gauthier discloses that the droplets output are less than 10 micrometers in diameter (col. 5, ln. 30-35).

As to claim 11, Gauthier discloses the claimed invention, as discussed in claims 1 and 9 above, including that the delivery system includes a pressurization system 50 that controls the pressure of the pharmaceutical product (the pressure of the product being delivered is controlled by the blower 50, col. 6, ln. 44-48).

As to claim 13, Gauthier discloses a MEMS cover (element 31 can be considered a MEMS cover since it covers the driver element 12, 120).

As to claim 19, Gauthier discloses that the delivery system includes a section 52 for insertion into a human orifice (tube 52 is capable of being inserted into the mouth of a user to deliver the product).

As to claim 21, it appears that Gauthier's device is capable of creating a capillary wave, as discussed in claim 1 above, that would be resultant of relaxation of a principal mound.

As to claim 26, Gauthier discloses the claimed invention, as discussed in claims 1, 9, and 11 above, including a pharmaceutical product (within vessel 26).

**3. Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (US Patent No. 5,485,828).**

Hauser discloses a method of delivering pharmaceutical product comprising: generating a pulse of acoustic energy, the pulse having a short duration and low frequency such that the pulse of acoustic energy generates capillary waves, at least one capillary wave ejecting at least one droplet of pharmaceutical product (col. 1, ln. 27-35); Focusing the acoustic energy between the pulse of acoustic energy and the capillary waves; and positioning the droplet near a human orifice for inhalation into a respiratory system (col. 1, ln. 16-19); wherein the capillary wave is formed by the relaxation of at least one principle mound of pharmaceutical product (col. 1, ln. 35) generated by focusing the pulse of acoustic energy (col. 2, ln. 51-61).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**5. Claims 3, 6, 14-16, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gauthier, in view of Sweet (US Patent No. 5,231,426).**

As to claim 3, Gauthier discloses the claimed invention except that the acoustic lens is a fresnel lens. However, Sweet teaches the use of a fresnel lens to focus acoustic waves in order to form microdroplets at the surface of a liquid (col. 3, ln. 4-6).

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Gauthier to include the fresnel type lens in place of the acoustic lens as taught by Sweet in order to provide a suitable alternate means for focusing the acoustic waves generated by the transducer since it appears that Gauthier's apparatus would perform equally well with a fresnel lens in place of the acoustic lens.

As to claim 6, Gauthier discloses the claimed invention, including a portable energy source 14 to provide energy to the first driver element 12, 120, and an ejector but does not disclose a second driver element coupled to the energy source to provide drive signal to the ejectors that eject droplets of the pharmaceutical product. However, Sweet teaches multiple driver elements 15 (Fig. 3) coupled to an energy source that provides drive signals to ejectors to eject droplets (col. 3, ln. 31-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Gauthier to include the second driver element coupled to the energy source as taught by Sweet in order to eject more droplets to deliver the pharmaceutical product more efficiently.

As to claim 14-16, the modified apparatus of Gauthier discloses the claimed invention, as discussed in claims 1, 3, 4, and 6 above, including a plurality of lenses (Sweet shows several lenses 19, one for each transducer, Fig. 3) and a delivery system (the housing of the device of Gauthier, Fig. 1) to maintain a reservoir 26 of pharmaceutical product, the reservoir to receive energy from the lenses 121 to cause ejection of a plurality of droplets. Gauthier lacks detailed description as to a distance

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from a top surface of a lens (19 of Sweet) and a surface of the liquid product being less than 150 micrometers. However, Sweet teaches a distance from a top surface of a lens 19 (Fig. 3) and a surface of the liquid product being less than 150 micrometers (since Sweet recites the spacing of the lenses to be on the order of 50 microns (col. 3, ln. 39-50), one can deduce, from looking at Fig. 3, the teaching of the distance between each lens and the surface of the liquid to be less than 150 microns). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Gauthier so that the spacing between the lens and the surface of the pharmaceutical product is less than 150 micrometers in order to provide a suitable spacing to eject droplets since it appears that Gauthier's apparatus would perform equally well with a spacing of this size.

As to claim 22, the modified apparatus of Gauthier discloses that the droplets have a diameter of less than 5 micrometers (see Gauthier, col. 5, ln. 42-43).

**6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gauthier, in view of Elrod (US Patent No. 4,751,530).**

Gauthier discloses the claimed invention except for a second acoustic lens to focus energy generated by the first driver element and cause ejection of a second droplet of pharmaceutical product. However, Elrod teaches a droplet ejection device that includes a second acoustic lens 12i (Fig. 5) in addition to a first lens 12a which focuses energy generated by a first driver element 23 to cause ejection of a second droplet. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Gauthier to include the second

acoustic lens as taught by Elrod in order to eject more droplets at the same time to deliver more product more efficiently.

**7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gauthier, in view of Blau (US Patent No. 5,372,126).**

Gauthier discloses the claimed invention, including an ejector head 26 (Fig. 6) that covers the acoustic lens 121 (col. 4, ln. 50-61) that is sterilized (col. 6, ln. 17-18), but does not disclose that the sterilization is done by an ultraviolet radiation source (col. 1, ln. 48-50). However, Blau discloses sterilizing an object using ultraviolet radiation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Gauthier so that the ejector head is sterilized by UV radiation in order to provide a suitable means for insuring the product is clean and safe for use.

**8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gauthier, in view of Sweet, as applied to claim 14 above, and further in view of Ivri (6,205,999).**

The modified apparatus of Gauthier discloses the claimed invention except for a circuit that detects air flow into a patient's lungs. However, Ivri teaches a flow sensor 24 (fig. 2) for detecting flow into a patient (col. 7, ln. 51-53) that couples a transducer 26 to a circuit (col. 7, ln. 53-56). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Gauthier with a



circuit that detects air flow as taught by Ivri in order to provide the advantage of preventing accidental dosing of pharmaceutical product.

### ***Response to Arguments***

Applicant's arguments, see page 12 of the remarks, filed April 7, 2011, with respect to claim 7 have been fully considered and are persuasive. The rejection of claim 7 under 35 USC 103 as being obvious over Gauthier in view of Sweet has been withdrawn.

Applicant's arguments filed April 7, 2011 with respect to claims 1-6, 9-17, 19, and 21-26 have been fully considered but they are not persuasive.

Applicant argues on page 8 of the remarks that Gauthier does not disclose that the nebulizer outputs a droplet from a capillary wave. However, the argument is not well taken because it appears that Gauthier's device is capable of performing this function. Gauthier discloses the structural limitations to the claim and does not disclose any structure which would prevent the device from being capable of performing this function.

Applicant further argues on page 8 of the remarks that Gauthier does not disclose a driver element generating acoustic energy in pulses that are of a short duration and frequency. However, the argument is not well taken because Gauthier's oscillator 14 appears capable of generating energy to the driver element (transducer 12) in the form of pulses that are of short duration and low frequency. As further evidence of this, Nakai et al (US Patent No. 4,319,155) refers to Gauthier's device as a "pulse oscillating circuit" (see col. 1, ln. 22-25). Therefore, it appears that one of ordinary skill

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in the art would recognize Gauthier's device as being capable of generating pulses which are of short duration. Furthermore, since Gauthier's device allows adjustment of the frequency, it is capable of generating relatively low frequencies.

Applicant argues on page 9 of the remarks that Hauser does not disclose that the capillary waves are created by a pulse of acoustic energy. However, the argument is not well taken because the claim only requires that one pulse be produced and it is the examiner's position that simply turning the device on and then off would create a pulse. Therefore, in light of this, it appears that Hausier's method would create at least one pulse that could be considered of short duration and low frequency.

Applicant argues on page 8 of the remarks that Hauser's device produces microdroplets from a jet-shaped fountain, not a capillary wave and points to col. 2, ln. 58-60 in which Hausier discloses his droplets are output from a jet. However, the argument is not well taken because the claim is cited as being anticipated by Hausier's disclosure of the prior art, not his invention. In the prior art, Hausier discloses that droplets are created from capillary waves (col. 1, ln. 33-35). Therefore, the claimed limitation is still met.

Applicant argues on page 8 of the remarks that Hausier does not disclose focusing the acoustic energy between the pulse of acoustic energy and the capillary waves and points to the Figures to show that Hausier's device does not anticipate this limitation. However, again, Hausier's device is not relied upon as anticipating the claim, but rather his description of the prior art. In col. 1, ln. 57-59, Hausier discloses focusing the waves using a Fresnel type lens which anticipates the claimed limitation.

Applicant argues on page 8 of the remarks that Hausier does not disclose positioning the droplet near a human orifice for inhalation into a respiratory system. However, the argument is not well taken because Hausier's disclosure relates to devices for delivering droplets to the nose, throat or bronchi. Therefore, the droplet would inherently have to be positioned near a human orifice (i.e., the nose) in order to be inhaled, thus anticipating the claim limitation.

Applicant argues on page 12 of the remarks that since Sweet does not disclose a capillary wave, the lens is not positioned between the first driver element and the capillary wave. However, the argument is not well taken because Sweet is not relied upon to teach or disclose these limitations (Gauthier is cited as disclosing these features). Sweet is instead relied upon to teach an alternative type of lens for focusing acoustic energy (Fresnel type lens) in place of Gauthier's lens.

Applicant argues on page 13 of the remarks that Elrod does not disclose ejection of a second drop of pharmaceutical product, since Elrod's invention relates to the ejection of ink for printing. However, both Gauthier and Elrod relate to droplet ejection and are therefore, related arts. Furthermore, Elrod is relied upon to teach a second lens in order to eject a second droplet which one of ordinary skill in the art would recognize as a benefit in droplet ejection of any substance (ink or pharmaceutical product) in order to more efficiently dispense a product.

Applicant argues on page 13 of the remarks that Blau does not disclose an ultraviolet source to sterilize an ejector head. However, as stated in the rejection of claim 12 above, Gauthier discloses sterilizing the ejector head and Blau is only relied

upon to teach ultraviolet radiation (which inherently would have an ultraviolet source) as an alternative means to for sterilization. Therefore, one of ordinary skill in the art upon seeing the Gauthier and Blau references would be able to come to the claimed invention of using ultraviolet radiation as a means to sterilize the ejector head.

Finally, applicant argues on page 14 of the remarks that Ivri does not disclose detecting the air flow when a critical air speed is reached. However, the argument is not well taken because Ivri's inhalation flow sensor detects inhalation and upon detection, sends a signal to a circuit to activate a transducer (piezoelectric member 26). The flow sensor is inherently going to have a sensitivity to which it can detect flow. Therefore, the critical air speed would be set by the sensitivity of the flow sensor.

#### ***Allowable Subject Matter***

9. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Romain (US 4,001,650).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE L. SKORUPA whose telephone number is (571)270-1479. The examiner can normally be reached on Monday - Friday, 8:00 a.m. - 5:00 p.m., EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/VALERIE L SKORUPA/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771